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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,564

10/15/2004

Rajendra K Joshi

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04/09/2007

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EXAMINER

VALENROD, YEVGENY

ART UNIT

PAPER NUMBER

1621

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/511,564

Applicant(s)

JOSHI ET AL.

Examiner

Yevgeny Valenrod

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1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 3,6,16 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,7-15 and 18-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/24/05; 8/18/05; 8/04/05</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 4, 5, 7-15 and 18-26, drawn to compounds, pharmaceutical preparation and method of use of compounds corresponding to formula (I) as described in claim 5.

Group II, claims 3, 4, 6, 7-13, 16-26, drawn to drawn to compounds, pharmaceutical preparation and method of use of compounds corresponding to formula (II) as described in claim 6.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The compounds of formula (I) are structurally different from compounds of formula II. The two types of compounds presented in the claims are not overlapping in scope and are not obvious variants of one another. Since the structure of the oligomers is what links the claims

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together, groups I and II are lacking common special technical feature which results in lack of unity.

3. During a telephone conversation with Konstantin Linnik on 3/27/07 a provisional election was made with traverse to prosecute the invention of Group I, claims 1, 2, 4, 5, 7-15 and 18-26. Affirmation of this election must be made by applicant in replying to this Office action. Claims 3, 6, 16 and 17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

4. Claims 12, 13, 18-26 are objected to under 37 CFR 1.75(c) as being in improper form because they are multiple dependant claims that include dependence on multiple dependant claims 4 and 5. See MPEP § 608.01(n).

5. Objection is made to claims 7-13, 18-26 as containing non-elected subject matter. The claims are drawn to multiple inventions for reasons set forth in the above requirement for restriction. The claimed compounds, compositions, and methods that

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employ them present a variable core. Formula (II) in claim 6 corresponds to compounds drawn to the non-elected invention.

Claim Rejections - 35 USC § 101

6. Claims 18, 19 and 26 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

7. Claims 18, 19 and 26 provide for the use of carbocyclic oligomers, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2, 4, 5, 7, 9, 12, 18-22, 25 and 26 rejected under 35 U.S.C. 102(b) as being anticipated by Schmidt-Dunker et al (US 3,920,837; for here on "Schmidt").

Schmidt discloses cyclohexane-1,2,3,4,5,6-hexacarboxylic acid and water-soluble salts thereof. The said acid meets the structural limitations of claims 1, 2, 4, 5, 7, 9, 12, 18-22, 25 and 26.

Claims 2 and 12 include limitation directed to preparation of the claimed compounds. Claims 2 and 12 are treated as product-by-process claims. The limitations directed to the process are not given patentable weight:

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same or obvious from the product of the prior art, the claim is unpatentable even though the prior art product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (MPEP § 2113).

Pharmaceutical compositions comprising cyclohexane-hexacarboxylic acid are described in column 2 lines 19-50. Limitation of the instant claims directed to intended use of the pharmaceutical preparations (claims 19, 21, 26) are not given patentable weight:

"It is well settled that the intended use of a composition or product (e.g. as a cosmetic composition) will not further limit claims drawn to a composition or product, so

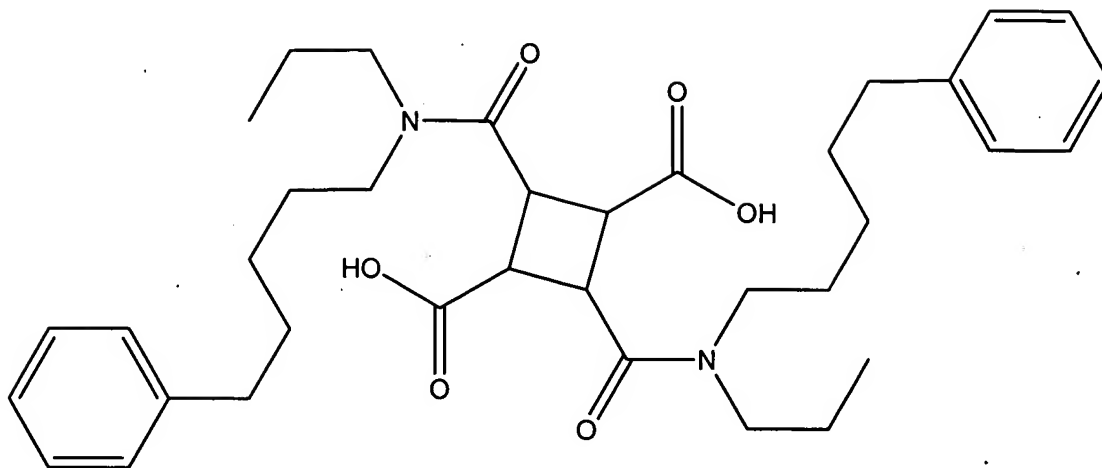
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long as the prior art discloses the same composition comprising the same ingredients in an effective amount as instantly claimed.” See, e.g., *Ex parte Masham*, 2 USPQ2d, 1647

9. Claims 1, 2, 4, 5, 7 and 9-14 rejected under 35 U.S.C. 102(b) as being anticipated by Griffin (US 3,139,395). Griffin discloses the tetramethyl ester of trans, trans, trans-1,2,3,4-cyclobutanetetracarboxylic acid (column 4, example 6 lines 30-32). Claims 2 and 12 are treated as product-by-process claims. The limitations directed to the process are not given patentable weight:

“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same or obvious from the product of the prior art, the claim is unpatentable even though the prior art product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (MPEP § 2113).

10. Claims 1, 2, 4, 5, 8, 12, and 18-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Stein et al. (US 5,631,401). Stein et al disclose 1,3-Di[N-propyl-N-(5-phenylpentyl)aminocarbonyl]cyclobutane-2,4-dicarboxylic acid (column 35, Example 38):



The above structure meets the structural limitations of claims 1, 2, 4, 5, 8 and 12. R_3 and R_4 are alkyl and aralkyl radicals. Claims 2 and 12 are treated as product-by-process claims (see reasoning and citation in paragraph 8). Stein et al. also disclose pharmaceutical compositions of their compounds (column 96, claims 11-14). The intended use of the instantly claimed pharmaceutical preparations is not given any patentable weight (see reasoning in paragraph 8). Methods of administering the compounds are described in column 88, line 31- column 89, line 11 and include: oral administration (column 88, lines 32-33), tablets and capsules (column 88, line 63).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt-Dunker et al. (US 3,920,837).

Scope of prior art

Schmidt discloses cyclohexane-1,2,3,4,5,6-hexacarboxylic acid and water-soluble salts thereof.

Ascertaining the difference between prior art and claim 15

Claim 15 indicates relative stereochemistry of the substituents on the cyclohexyl ring as being trans for every adjacent substituent. Schmidt discloses a racemic mixture and fails to disclose the relative stereochemistry of the substituents on the alkyl ring.

Obviousness

In order to patent an optical isomer, it is necessary to show that they possess "...qualities [which] are utterly unobtainable" in the racemic mixture. Sterling Drug v. Watson, 108 USPQ 37. Note also, Pfizer v Int. Rectifier Corp., 190 USPQ 273, 280;

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Lilly v. Generex, 174 USPQ 65. See also In re Volweiler, 146 USPQ 137 (requiring that the claimed component of an old mixture "be so different in properties and uses as to be in effect a new compound"). A mere improvement in properties does not necessarily suffice. In re Weijland, 69 USPQ 449; Ex parte Hald, Paper 15 in U.S. Patent No. 2,647,145; Ex parte Cavallito, 89 USPQ 449. The reference does not have to suggest resolution of the racemate. One of ordinary skill in the art is presumed to be able to do so. The expectation with regard to enantiomers is that activities as the pertain to living systems are expected to be different. In re Adamson, 272 F.2d 952, 125 USPQ 233 (CCPA 1960).

Applicant has not shown that the compound of claim 15 possesses qualities that are unobtainable in the racemic mixture. The compound of claim 15 is therefore obvious over Schmidt.

Conclusion

Claims 1-26 are pending.

Claims 3, 6, 16 and 17 are withdrawn.

Claims 1, 2, 4, 5, 7-15, 18-26 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

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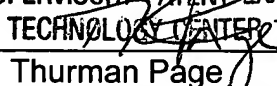
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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